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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,111	03/02/2004	Richard Cornelius	21747-304	3780

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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/792,111

Applicant(s)

CORNELIUS ET AL.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30 and 37-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed:
- 6) ☒ Claim(s) 24-30 and 37-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10-29-04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The Applicant has elected claims 24-30 and added claims 37-50, which are all examined below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1. Claims 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claimed phrase "expandable electrode arms" is inconsistent with the specification, which reads "retractable electrode arms". Correction is required.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2. Claims 24,25,37,38,43, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahnen et al. (5,980,519).**

Independent claims 24, 37, and 43 (all parentheticals refer to Hahnen)

24. A positioning device for an ablation tool (110; figure 4) comprising:

a flexible elongated tube (180);

a sheath (174) movable back and forth along said elongated tube;

at least two expandable electrode arms (184a, 184b);

a flexible conforming strip (199) extending between said at least two expandable electrode arms (depicted in figure 4);

said flexible conforming strip (patented title, "probe with **variable morphology** electrode"; col. 2:33-35) having sufficient flexibility so as to substantially readily conform to the shape of a target ablation site upon contact of said conforming strip with said target ablation site;

and an ablation mechanism (col. 4:38-39) included on said conforming strip.

37. A method of positioning an ablation device within a body comprising:

providing an ablation tool (110; figure 4) having an elongated body and a flexible electrode (199) on a distal end of said ablation tool;

directing said distal end of said ablation tool to a target tissue area within said body (uterus);

expanding said flexible electrode;

contacting said flexible electrode to substantially conform (col. 3:12-15) to a surface of said target tissue area (uterus);

ablating at least a surface of said target tissue area.

43. An ablation positioning device (110, figure 4) for ablating target tissue comprising:
an elongated member (180) sized and shaped to be positioned within the lumen
(uterus) of a body, said elongate member including a distal end (188);
a first arm member (184a) disposed on said distal end of said elongated member;
a second arm member (184b) disposed on said distal end of said elongated
member; and
a flexible ablation member (199) extending between said first arm member and
said second arm member;
wherein said flexible ablation member is conformable (patented title, "probe with
variable morphology electrode"; col. 2:33-35) to at least a part of a
shape of said target tissue (uterus) and to ablate at least a part of said target tissue.

Dependent claims

25. A positioning device according to claim 24, wherein said flexible conforming strip
comprises a conforming electrode strip (199, col. 4:37-38).

38. The method of claim 37 wherein providing an ablation tool includes providing a
flexible electrode (199) that has at least two arm members (184a, 184b) configured to
expand (inherent to the design depicted in figure 4) said flexible electrode.

44. The ablation positioning device of claim 43 wherein said flexible ablation member includes an electrode strip (199, col. 4:37-38).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 26-30, 39, 41-42 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahnen in view of Jahns et al. (6,558,382).

Hahnen neglects to expressly disclose electrode needles for tissue fixation.

Jahns discloses in an analogous device (512, figure 5; col. 9:44-60), bipolar needle electrodes (figure 5, 522) to improve connection to the targeted tissue. The Office contends that that placing the Jahns needle electrodes onto the electrode strip in Hahnen would have been obvious. It is noted that Hahnen discloses numerous embodiments many of which include a *coiled* electrode as depicted in Hahnen figure 4, **however**, the patent also discloses *flat* electrodes in lieu of the coiled electrode (col. 7:60-65) making the addition of the bipolar electrodes in Jahns to the flat Hahnen electrode, seamless. The placement of Jahns' needle electrodes onto a flat electrode

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described in Hahnen would yield a very similar device to that seen in the Applicant's figures 23b and 23c, which best depicts the claimed invention.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Hahnen in view of Jahns by including Jahns bipolar needle electrodes onto the conforming electrode member in Hahnen. The motivation would be to improve targeted tissue contact.

Dependent claims (parentheticals refer to Jahns unless stated otherwise)

26. A positioning device according to claim 24, wherein a plurality of ablation electrode needles (522) are disposed on said conforming strip (See Jahns figure 5).

27. A positioning device according to claim 24, wherein a plurality of bi-polar ablation electrode needles (col. 9:48) are disposed on said conforming strip.

28. A positioning device according to claim 24, wherein each of said at least two expandable arms include a distal tip, wherein a tissue fixation needle is disposed on said distal tip of at least one of said expandable arms (obvious with the substitution of Jahns needles onto the flat Hahnen electrode).

29. A positioning device according to claim 28, wherein a tissue formation needle is disposed on said distal tip of each of said expandable arms (obvious with the substitution of Jahns needles onto the flat Hahnen electrode).

30. A positioning device according to claim 24, wherein one anchoring needle (522) is disposed on said flexible conforming strip.

39. The method of claim 38 wherein the providing of a flexible electrode includes providing a tissue fixation needle (522) on a distal tip of at least one of said at least two arm members (obvious with the substitution of Jahns needles onto the flat Hahnen electrode).

41. The method of claim 37 wherein the providing of a flexible electrode includes providing a plurality of ablation electrode needles (522) on said flexible electrode.

42. The method of claim 37 wherein the providing of a flexible electrode includes providing a plurality of bipolar ablation electrode needles (col. 9:48) on said flexible electrode.

45. The ablation positioning device of claim 43 wherein a plurality of electrode needles (522) are disposed on a surface of said flexible ablation member.

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46. The ablation positioning device of claim 43 wherein a plurality of bipolar electrode (col. 9:48) needles are disposed on said flexible ablation member.

47. The ablation positioning device of claim 43 wherein said first arm member includes a tissue fixation needle disposed on a distal tip of said first arm member (obvious with the substitution of Jahns needles onto the flat Hahnen electrode).

4. Claims 40 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahnen in view of Jahns et al. (6,558,382) and further in view of Lundkvist et al. (6,625,486).

Neither Jahns nor Hahnen expressly disclose retractable needle electrodes.

Lundkvist discloses a catheter with retractable needle electrodes (12, figures 2 and 2b). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Hahnen in view of Jahns and further in view of Lundkvist by including retractable needle electrodes onto the conforming electrode member in Hahnen. The motivation would be to prevent needle electrodes from causing luminal irritation as disclosed in Lundkvist col. 6:44-48.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
June 12, 2005


MICHAEL PEFFLEY
PRIMARY EXAMINER